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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,434	09/09/2008	Igor E. Bondarev	ALTS.0006US2	5607
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Juan Carlos A. Marquez c/o Stites & Harbison PLLC 1199 North Fairfax Street Suite 900 Alexandria, VA 22314-1437				
EXAMINER				
MCDONALD, JENNIFER SUE PIRAK				
ART UNIT		PAPER NUMBER		
1635				
NOTIFICATION DATE		DELIVERY MODE		
09/27/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

iplaw@stites.com

Office Action Summary

Application No.

10/586,434

Applicant(s)

BONDAREV ET AL.

Examiner

JENNIFER PITRAK McDONALD

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/27/11.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-20, 22-24 and 62-64 is/are pending in the application.
- 4a) Of the above claim(s) 3-5 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-16, 22-24 and 62-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date 9/9/08; 4/5/11
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Remarks

Claims 1-16, 18-20, 22-24, and 62-64 are pending. Claims 3-5 and 18-20 are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejections and/or objections presented herein are either newly applied or maintained and are the only rejections and/or objections currently outstanding.

Compliance with 37 C.F.R. § 1.121

The amendments to the claims filed 06/27/2011 do not comply with 37 C.F.R. § 1.121. Specifically, claim 2 is labeled "withdrawn" but is under consideration and claim 23 has been amended but the changes are not indicated with proper markings. In the interest of compact prosecution, the amendments have been entered. Applicant is hereby notified that any future amendments that do not comply with 37 C.F.R. § 1.121 may not be entered.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing. The Oath identifies United States Application No. 10/758329 under foreign priority. This U.S. application is not a foreign application. Furthermore, the Oath does not indicate the priority claim to U.S. Provisional Application 60/440,988. The first paragraph of the specification indicates that such priority is claimed.

Response to Arguments

Applicant submitted an Application Data Sheet on 06/27/2011 in an effort to address the objection to the Oath. The ADS filed 06/27/2011 is not accepted because it is not properly labeled "Supplemental ADS", per MPEP 601.05.

Claim Objections

Claims 6 and 7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims improperly refer to "the organic compound" of claim 1. The claims should depend from Claim 2.

Claim Rejections - 35 USC § 103 - maintained

Claims 1, 2, 6-16, 22-24, and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo, *et al.* (U.S. Patent 5,631,236, of record) ("Woo") as evidenced by Bryan,

et al. (2000, Nat. Med., v.3:1271-4) (of record, item CV on 09/09/2008 IDS) ("Bryan"). This rejection is maintained for the reasons of record.

Response to Arguments

Applicant summarizes the teachings of Woo (top of page 8 of 6/27/11 response).

Applicant argues that Woo does not teach or suggest a method of treating solid tumors or cancers from telomerase negative cells with ganciclovir without the delivery of prodrug converting enzyme gene and expression of the gene. Applicant argues that Woo does not teach or render obvious that LIRT is involved in the lengthening of telomeres in cancer cells and that ganciclovir is an inhibitor of this enzyme. Applicant concludes that therefore the skilled artisan would not be led to use ganciclovir to block telomere lengthening in telomerase negative cells as claimed. This is not persuasive. As stated in the rejection, it would have been obvious to the skilled artisan to use ganciclovir to treat osteosarcoma, the cells of which include ALT⁻ and ALT⁺ cells, as taught by Bryan. ALT⁺ cells inherently exhibit LIRT activity. Therefore, in performing the ganciclovir treatment of osteosarcoma as taught by Woo, the skilled artisan would also be performing the instantly claimed methods. The LIRT inhibition by ganciclovir would occur upon performing the methods taught by Woo, regardless of whether the skilled artisan was aware of the LIRT-inhibitory activity of ganciclovir. This is relevant to Applicant's further argument at paragraph 3 on page 8 of the 6/27/11 response that Brian does not teach or render obvious that LIRT is involved in the lengthening of telomeres. The skilled artisan need not know that LIRT is involved in the lengthening of telomeres to perform the methods of Woo.

Applicant then contends that hindsight was used to establish the *prima facie* case of obviousness (paragraph spanning pages 8 and 9 of the 6/27/11 response). This is not persuasive.

The specification describes an inherent feature of ALT⁺ cells, i.e. that L1RT is responsible for ALT. Woo teaches a method of treating ALT⁺ cells with ganciclovir. The fact that such cells rely on L1RT activity for ALT has no bearing on the obviousness of performing the methods of Woo.

Applicant argues that there is no suggestion in the prior art for using ganciclovir without the HSVTK expression to treat an individual suffering from cancer with cells that are telomerase positive or telomerase negative cells showing ALT and, therefore, there is no reasonable expectation of success (p.9 of 6/27/2011 response). Applicant elaborates on this point, emphasizing that the methods of treating cancer with ganciclovir taught by Woo require HSV-TK expression (pages 9-11 of 6/27/11 response). This is not persuasive. Applicant is arguing limitations that are not present in the claims, namely the exclusion of HSV-TK expression in the cancer cells of the ganciclovir-treated individual.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the

scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 6-16, 22-24, 62, 63, and 64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 59-85 of copending Application No. 12/070923. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '923 application are directed to species of the instant claims and therefore the '923 claims anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 6-16, 22-24, 62, 63, and 64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 16-33 of copending Application No. 11/920668. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '668 application are directed to the same methods of treating cancer in cells showing ALT activity comprising administering ganciclovir and other nucleoside analogs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 6, 10, 14, 16, and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 46 of copending

Application No. 12/225199. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the '199 application is directed to a method of treating cancer by administering a nucleoside analog LIRT inhibitor or inhibitors, which is also instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant has presented no argument traversing the Double Patenting rejections.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK MCDONALD whose telephone number is

(571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita can be reached on 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER PITRAK MCDONALD/
Primary Examiner, Art Unit 1635